are hereby withdrawn as of November 18, 2024. Introduction or delivery for introduction into interstate commerce of Helium, USP, without an approved new drug application or an approved new animal drug application violates sections 505(a), 512(a), 301(a), and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a), 360b(a)(1), 331(a), and 331(d)). Any Helium, USP manufactured by Linde, Inc. pursuant to these applications that is in inventory on November 18, 2024 may continue to be dispensed until the inventories have been depleted or the drug product has reached its expiration date or otherwise become violative, whichever occurs first.

Dated: October 9, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24106 Filed 10–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2303]

Core Patient-Reported Outcomes in Cancer Clinical Trials; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Core Patient-Reported Outcomes in Cancer Clinical Trials.'' This final guidance provides recommendations to sponsors regarding the collection of a core set of patient-reported clinical outcomes (herein referred to as core patient-reported outcomes) in cancer clinical trials and related considerations for instrument selection and trial design. This final guidance focuses on patient-reported outcome (PRO) measures and is specific to registration trials for anti-cancer therapies intended to demonstrate an effect on survival, tumor response, or delay in the progression of a malignancy.

DATES: The announcement of the guidance is published in the **Federal Register** on October 18, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–2303 for ''Core Patient-Reported Outcomes in Cancer Clinical Trials.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Vishal Bhatnagar, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2113, Silver Spring, MD 20993–0002, 240–402–3696; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7910.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Core Patient-Reported Outcomes in Cancer Clinical Trials.'' This final guidance provides recommendations to sponsors regarding the collection of a core set of PROs in cancer clinical trials and related considerations for instrument selection and trial design. The final guidance recommendations supplement previous guidance on use of PRO measures in clinical trials by providing additional considerations specific to the cancer clinical trial setting. The final guidance is intended to facilitate generation of high-quality data on a core set of patient-reported symptom and functional impacts that are important contributors to a patient's health-related quality of life.

Although this final guidance focuses on PRO measures, some of the recommendations may be relevant to other clinical outcome assessments (*i.e.,* clinician-reported outcome, observer-reported outcome, performance outcome) in cancer clinical trials. The final guidance is specific to registration trials for anti-cancer therapies intended to demonstrate an effect on survival, tumor response, or delay in the progression of a malignancy.

Cancer clinical trials typically employ standardized efficacy assessments using overall survival and tumor measures, and safety assessments provided by clinician reporting of adverse events. FDA acknowledges the added value of incorporating PRO measurement of symptoms and functional impacts into the benefit/risk assessment in appropriately designed trials; however, heterogeneity in PRO assessment strategies has lessened the regulatory utility of PRO data from cancer trials. Systematic assessment of a core set of PROs can facilitate high-quality data on patient-reported symptoms and functional impacts. In published literature, FDA authors have previously described a core set of PROs that may be important contributors to a patient's health-related quality of life and that may be sensitive to the effect of the disease and treatment under study.

FDA is issuing this final guidance to provide FDA's current thinking on the core PROs, considerations for instrument selection to measure the core PROs, trial design considerations such as assessment frequency, and labeling considerations. The core PROs recommended in the guidance are disease-related symptoms, symptomatic adverse events, overall side effect impact summary measure, physical function, and role function.

In the **Federal Register** of June 10, 2021 (86 FR 30944), FDA announced the availability of the draft guidance of the same title dated June 2021. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include recommendations to consult FDA when selecting adverse events for reporting, edits to include hematological malignancies, and minor, editorial changes to improve clarity.

This final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This final guidance represents the current thinking of FDA on ''Core Patient-Reported Outcomes in Cancer Clinical Trials.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 11, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24111 Filed 10–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–0761]

Determination That TAVIST (Clemastine Fumarate) Tablet, 2.68 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that TAVIST (clemastine fumarate) tablet, 2.68 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or